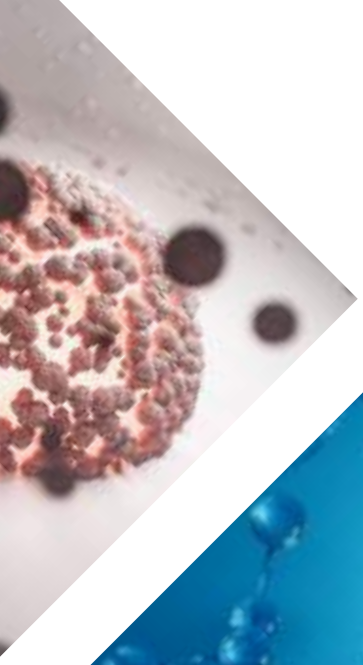
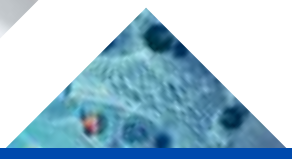
INFO FLIP BOOK



cerexio

EBR Systems for Biotech and Cell Therapy Manufacturing Implementation



info@cerexio.com www.cerexio.com +65 6762 9293

EBR Systems for Biotech and Cell Therapy Manufacturing Implementation

Introduction

Biotech and cell therapy manufacturing environments require highly controlled production workflows, strict regulatory compliance, and detailed process documentation. Traditional paper-based batch recording methods create operational bottlenecks, increase human error risks, and complicate audit readiness. Electronic Batch Record (EBR) systems provide a digital framework for capturing, validating, and managing manufacturing records in real time.

Why EBR Systems Are Critical for Cell Therapy Manufacturing

Cell therapy production involves highly sensitive biological materials, patient-specific manufacturing workflows, and complex quality assurance requirements. EBR systems improve traceability, reduce manual documentation errors, and enable faster review-by-exception processes for manufacturing teams.

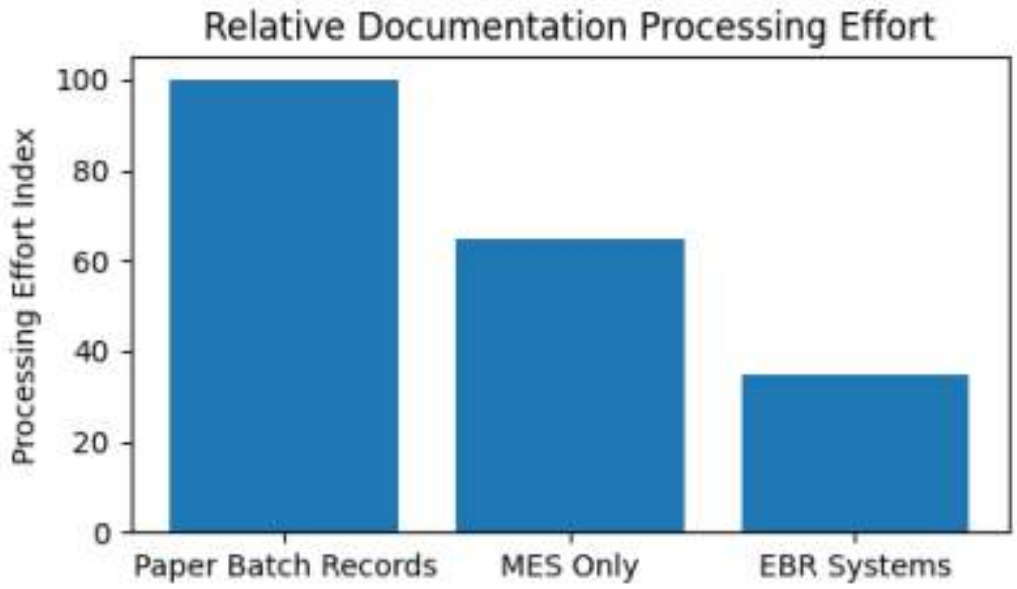
Key Stage	EBR Function	Key Benefits	Implementation Considerations
1. Early Process Development	Low-volume, high-control process validation	Rapid iteration, scalability assessment, high data quality	Define CQAs, DoE studies, select EBR platform
2. Scale-Up & Optimization	Process parameter optimization and scale translation	Improved yield and consistency, risk reduction, robust process design	Use PAT tools, model scale-up, verify performance
3. Engineering & Process Design	Process modeling, equipment integration, and control strategy development	Efficient design, reduced engineering risk, regulatory alignment	Integrate with control systems, ensure data integrity
4. GMP Manufacturing & Commercialization	Process monitoring, continuous improvement, tech transfer support	Consistent quality, regulatory compliance, faster time to market	Validate process, ensure GMP compliance, ongoing monitoring

info@cerexio.com www.cerexio.com +65 6762 9293

EBR Systems for Biotech and Cell Therapy Manufacturing Implementation

Key Applications in Biotech Manufacturing

- Digital batch execution and review-by-exception workflows.
- Automated deviation and exception tracking.
- Electronic signatures and audit trail management.
- Real-time environmental monitoring integration.
- GMP compliance documentation and validation.
- Process parameter traceability for personalised medicine manufacturing.
- Integration with laboratory and quality management systems.



Typical EBR Workflow

1. Manufacturing Data Collection
2. Real-Time Validation and Verification
3. Automated Compliance Checks
4. Batch Review and Exception Handling
5. Electronic Release and Reporting

info@cerexio.com www.cerexio.com +65 6762 9293

EBR Systems for Biotech and Cell Therapy Manufacturing Implementation

Artificial Intelligence and Advanced Analytics

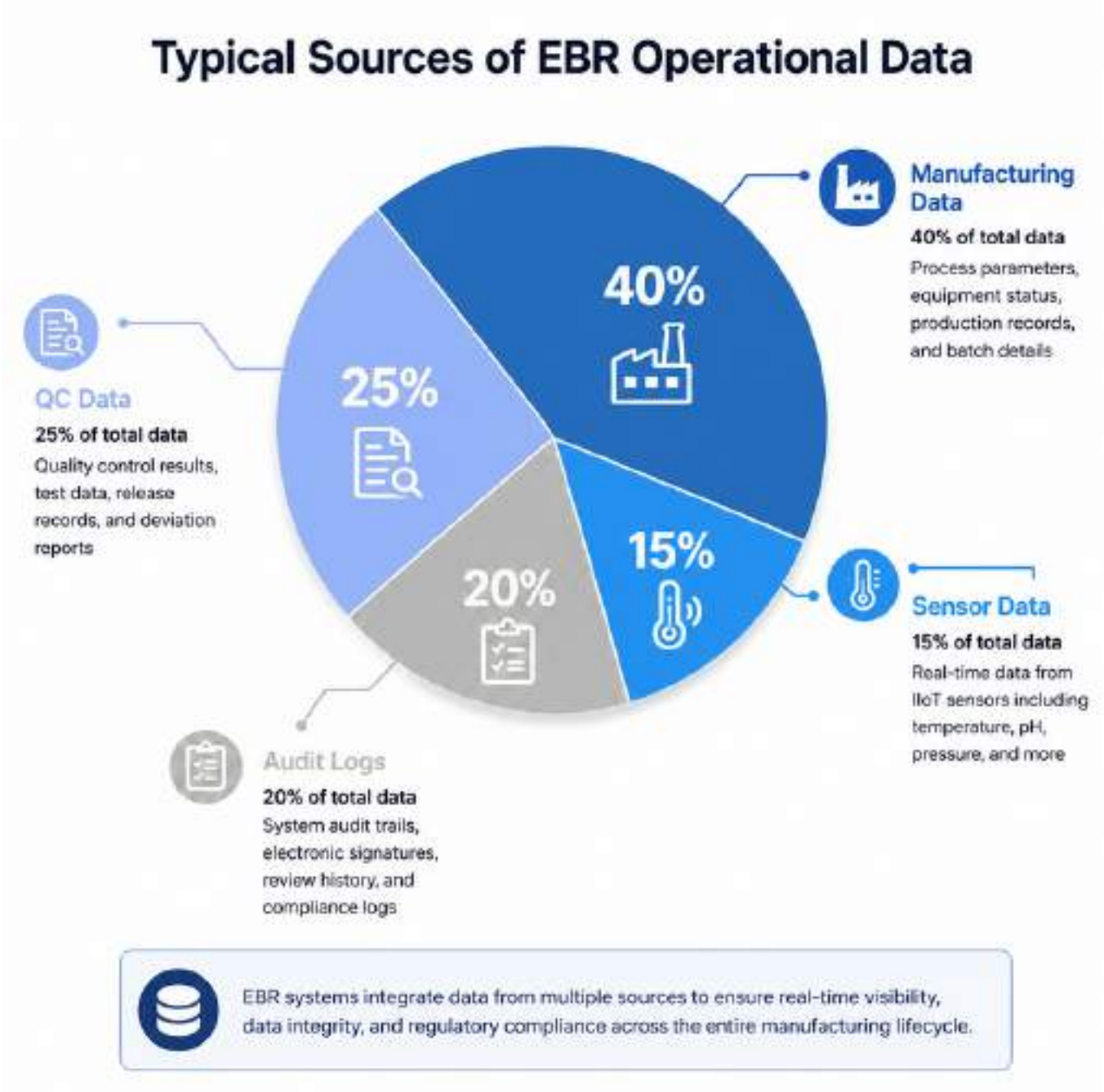
Artificial intelligence and advanced analytics are increasingly integrated into EBR environments to improve manufacturing quality, reduce review times, and support predictive operational insights. AI algorithms can identify unusual manufacturing trends, predict deviation risks, and support continuous process verification programs.

Capability	Traditional Batch Records	EBR-Based Manufacturing	Key Advantage
Documentation	**Manual paper records** Prone to loss, errors, and incomplete data	**Automated digital records** Structured, secure, and always complete	**Improved Data Integrity** Complete, accurate, and ALCOA+ compliant
Review Process	**Time-consuming reviews** Manual checks slow down batch release	**Review-by-exception** Risk-based reviews focus on critical deviations	**Faster Batch Release** Reduced review time and higher operational efficiency
Compliance	**Higher audit preparation effort** Manual compilation of documents	**Integrated compliance support** Built-in workflows, e-signatures, and regulatory alignment	**Stronger Compliance** Ready for inspections and regulatory audits
Traceability	**Fragmented records** Data scattered across systems and documents	**Centralized traceability** End-to-end tracking of materials, processes, and equipment	**Complete Traceability** Instant access to full audit trails
Error Detection	**Reactive identification** Issues found late in the process or after release	**Real-time validation** Automated checks and alerts prevent errors early	**Proactive Quality Control** Reduced errors, rework, and product recalls

info@cerexio.com www.cerexio.com +65 6762 9293

EBR Systems for Biotech and Cell Therapy Manufacturing Implementation

Typical Sources of EBR Operational Data


Typical Sources of EBR Operational Data
40%
25%
15%
20%
Manufacturing Data
40% of total data
Process parameters, equipment status, production records, and batch details
QC Data
25% of total data
Quality control results, test data, release records, and deviation reports
Sensor Data
15% of total data
Real-time data from IIoT sensors including temperature, pH, pressure, and more
Audit Logs
20% of total data
System audit trails, electronic signatures, review history, and compliance logs
EBR systems integrate data from multiple sources to ensure real-time visibility, data integrity, and regulatory compliance across the entire manufacturing lifecycle.

EBR Systems for Biotech and Cell Therapy Manufacturing Implementation

Regulatory Compliance and Validation

EBR implementations within biotech and cell therapy manufacturing must comply with strict global regulatory requirements, including FDA 21 CFR Part 11, GMP standards, ALCOA+ data integrity principles, and electronic signature regulations. Comprehensive system validation, cybersecurity management, and change control processes are essential for successful deployment.

Major Benefits

- Reduced batch review and release timelines.
- Improved manufacturing consistency and traceability.
- Enhanced audit readiness and regulatory compliance.
- Reduced documentation errors and manual interventions.
- Faster deviation management and corrective actions.
- Better scalability for personalised medicine production.
- Improved operational visibility across manufacturing facilities

Future Outlook

As biotech manufacturing environments continue to evolve, EBR systems will become increasingly integrated with AI analytics, digital twins, advanced automation platforms, and cloud-based manufacturing intelligence systems. Future smart factories will depend heavily on connected digital manufacturing ecosystems capable of supporting real-time decision-making, adaptive manufacturing, and highly personalised therapeutic production workflows.

Conclusion

EBR systems are transforming biotech and cell therapy manufacturing by enabling digitalised, compliant, and highly traceable production operations. By integrating automated workflows, AI-driven analytics, and real-time manufacturing visibility, organisations can improve operational efficiency, strengthen compliance, and support scalable advanced therapy manufacturing.

info@cerexio.com www.cerexio.com +65 6762 9293